UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION	MDL Docket No. 2409 Civil Action No. 12-cv-11711 (WGY)
WALGREEN CO., THE KROGER CO., SAFEWAY INC., SUPERVALU, INC. and HEB GROCERY CO. LP, Plaintiffs, v. ASTRAZENECA AB, AKTIEBOLAGET HASSLE, ASTRAZENECA LP, RANBAXY PHARMACEUTICALS, INC., RANBAXY, INC., RANBAXY LABORATORIES LTD., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., DR. REDDY'S LABORATORIES LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. **JURY TRIAL DEMANDED**

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs Walgreen Co., The Kroger Co., Safeway Inc., Supervalu Inc. and HEB Grocery Company LP bring this civil action against Defendants AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP (collectively "AstraZeneca"), Ranbaxy Pharmaceuticals, Inc., Ranbaxy, Inc., Ranbaxy Laboratories Ltd. (collectively "Ranbaxy"), Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc. (collectively "Teva"), Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "Dr. Reddy's") under the antitrust laws of the United States. For their Complaint, Plaintiffs allege as follows:

INTRODUCTION

1. This is a civil antitrust action seeking treble damages and injunctive relief arising out of Defendants' overarching scheme to monopolize the market for delayed-release esomeprazole magnesium, sold by AstraZeneca under the brand name Nexium. Nexium is a proton pump inhibitor prescribed to patients for the healing of erosive esophagitis, maintenance of erosive esophagitis, and treatment of symptomatic gastroesophageal reflux disease. AstraZeneca monopolized the market by entering into illegal market allocation conspiracies with, between, and among three generic manufacturers and potential competitors – Ranbaxy, Teva, and Dr. Reddy's (the "Generic Defendants") – that were disguised as patent litigation settlements. In reality, the settlements were payoffs by AstraZeneca to keep the generic drug makers, and potential competitors, off the market.

2. To protect its over $3 billion in annual Nexium sales from the threat of generic competition, AstraZeneca entered into non-competition agreements with each of the Generic Defendants, agreeing to pay the Generic Defendants substantial sums in exchange for their agreement to delay marketing their less expensive generic versions of Nexium for as long as six years or more, *i.e.*, until May 27, 2014 (the "Exclusion Payment Agreements" or simply the "Agreements"). The Generic Defendants did, in fact, delay marketing their less-expensive versions of Nexium; but for the Agreements, generic versions of Nexium would have been marketed in the United States as early as April 14, 2008, when the 30-month stay of the FDA approval of Ranbaxy's generic Nexium product expired.

3. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only difference between generic and brand name drugs is their price: generics are usually at least 40% less expensive than their brand counterparts when there is a single generic competitor, and

this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings to all drug purchasers.

4. Those same savings pose a grave threat to the monopoly profits of brand name drug companies such as AstraZeneca. FDA-approved, AB-rated generic versions of brand drugs typically take 80% or more of the unit sales of the brand product soon after generic entry. The Federal Trade Commission estimates that about one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product.

5. In order to delay the dramatic loss of its monopoly profits from Nexium, AstraZeneca engineered an overarching scheme whereby it would buy its way out of competition with the Generic Defendants and reduce the likelihood that its Nexium patents would be invalidated. Specifically, AstraZeneca agreed to pay the Generic Defendants to delay entering the market until May 27, 2014 and to drop their challenges to the Nexium patents. AstraZeneca and the Generic Defendants attempted to disguise or conceal these payments (frequently called "exclusion payments" or "reverse payments") as (i) compensation for supplying AstraZeneca with a portion of its Nexium supply, including esomeprazole magnesium, the active pharmaceutical ingredient ("API") in Nexium; (ii) payments for distributing authorized generic versions of two other AstraZeneca drugs, felodipine capsules (brand name, Plendil) and 40 mg omeprazole tablets (brand name, Prilosec) (with respect to Ranbaxy); and/or (iii) forgiveness of a contingent liability (with respect to Teva and Dr. Reddy's). AstraZeneca further effectuated a substantial reverse payment by agreeing not to launch its own authorized generic version of Nexium in competition with Ranbaxy's product for a substantial period of time. Defendants

intentionally concealed the true purpose and nature of these exclusion payments to avoid liability under the antitrust laws.

6. Although the Exclusion Payment Agreements purported to settle patent infringement suits that AstraZeneca filed against the Generic Defendants with respect to patents that purportedly cover Nexium, AstraZeneca used the strength of its wallet as opposed to the strength of its patents to obtain the agreement of the Generic Defendants not to launch their generic Nexium products. In light of the substantial possibility that AstraZeneca's Nexium patents would be invalidated and/or that the Generics' products would be adjudged non-infringing—in which case AstraZeneca would have been unable to keep generic versions of Nexium from swiftly absorbing the vast majority of sales of Nexium—AstraZeneca agreed to share its monopoly rents with the Generic Defendants as the *quid pro quo* for the Generic Defendants' agreement not to compete with AstraZeneca in the delayed-release esomeprazole magnesium market until May 27, 2014.

7. The Generic Defendants knew that it would be more profitable to be paid not to compete than to enter the market. Had the Generic Defendants all launched generic versions of Nexium, as they were preparing and poised to do, the competition among them would have driven down the price of generic Nexium. Once there are multiple generic versions of the same brand drug available, the generic behaves like a commodity, with little to distinguish one generic from another except price. While such competitive generic sales are still profitable, when there are multiple generics available for purchase, it is more profitable to be paid by the brand company not to compete. The Generic Defendants knew that by agreeing to delay entry in exchange for a portion of AstraZeneca's monopoly profits from Nexium, paid in the form of an Exclusion Payment, they could make more profit. And that is precisely what happened.

8. AstraZeneca and Ranbaxy also knew and intended that their Exclusion Payment Agreement would prevent still other generic companies from launching their own generic Nexium before Ranbaxy did, thereby creating a bottleneck. As the first-filer of an ANDA for generic Nexium, Ranbaxy is entitled to market its generic Nexium for 180 days free of competition from other generic Nexium products (except an authorized generic version of Nexium, if marketed by AstraZeneca). The operation of the Exclusion Payment Agreement between AstraZeneca and Ranbaxy blocked all other generic Nexium products from coming to market until 180 days after May 27, 2014 because, absent circumstances discussed below, the FDA will not approve subsequently-filed ANDAs until Ranbaxy's exclusivity period has run, which will not occur until 180 days after Ranbaxy launches. It also blocks an authorized generic version of Nexium until that same time, because as primary consideration to Ranbaxy for Ranbaxy's agreement to delay launch of generic Nexium, AstraZeneca agreed not to launch an authorized generic version of Nexium until 180 days after Ranbaxy launched.

9. Although it is possible that Ranbaxy could forfeit its 180 day exclusivity if it does not begin commercial marketing of its generic Nexium products within 75 days of a court decision that all of the patents for Nexium listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," are invalid or not infringed, AstraZeneca made sure that the second and third ANDA-filers for Nexium—Teva and Dr. Reddy's—would not break the bottleneck caused by its Exclusion Payment Agreement with Ranbaxy by obtaining such a court decision. When Teva and Dr. Reddy's neared a court determination on the issue of invalidity and/or non-infringement of the Nexium patents, AstraZeneca paid them, too, pursuant to the Exclusion Payment Agreements, to drop their patent challenges and stay out of the market until after Ranbaxy could enter the market under Ranbaxy's Exclusion Payment Agreement with AstraZeneca.

10. But for one or more of the unlawful Agreements at issue here, generic versions of Nexium would have entered the market as early as April 14, 2008, once the 30-month stay of FDA approval of Ranbaxy's generic Nexium products expired. The FDA granted tentative approval to Ranbaxy's generic Nexium products on February 5, 2008, which, absent the illegal Agreements complained of herein, would have been converted to a final approval on April 14, 2008. Thus, absent Defendants' illegal Agreements, Plaintiffs would have already been able to satisfy their delayed-release esomeprazole magnesium requirements at significantly lower prices, rather than being forced to pay high prices for branded Nexium because of Defendants' illegal agreements in restraint of trade.

11. Defendants' unlawful Exclusion Payment Agreements were designed to and did: (a) block the entry of less expensive generic versions of delayed-release esomeprazole magnesium in the United States; (b) fix or raise the prices of delayed-release esomeprazole magnesium products; (c) permit AstraZeneca to maintain a monopoly in the United States for delayed-release esomeprazole magnesium; (d) allocate 100% of the United States delayed-release esomeprazole magnesium market to AstraZeneca; and (e) allocate 100% of United States generic Nexium sales to Ranbaxy during the first 180 days of generic sales.

12. As alleged in more detail below, through their overarching anticompetitive scheme, Defendants violated § 1 and § 2 of the Sherman Act through their conspiracy to improperly maintain their market power by foreclosing competition from lower-priced generic versions of delayed- release esomeprazole magnesium.

JURISDICTION AND VENUE

13. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover threefold damages, injunctive relief, costs of suit and reasonable attorneys' fees for the injuries sustained

by Plaintiffs resulting from Defendants' unlawful foreclosure of the United States market for delayed-release esomeprazole magnesium (Nexium and its AB-rated generic equivalents). The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a).

14. Defendants transact business within this district and/or have an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, 28 U.S.C. §1391(b) and (c) and 28 U.S.C. §1407.

PARTIES

15. Plaintiff Walgreen Co. ("Walgreen") is an Illinois corporation having its principal place of business at 200 Wilmot Road, Deerfield, Illinois 60015. Walgreen owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Nexium. Walgreen brings this action in its own behalf and as the assignee of Cardinal Health, Inc. ("Cardinal") and AmerisourceBergen Drug Corporation, two pharmaceutical wholesalers, which during the relevant period purchased Nexium directly from Defendant AstraZeneca for resale to Walgreen and which have assigned or agreed to assign their claims arising out of those purchases to Walgreen.

16. Plaintiff The Kroger Co. ("Kroger") is an Ohio corporation having its principal place of business at 1014 Vine Street, Cincinnati, Ohio 45202. Kroger owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Nexium. Kroger brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Nexium directly from Defendant AstraZeneca for resale to Kroger and which has assigned its claims arising out of those purchases to Kroger.

17. Plaintiff Safeway Inc. ("Safeway") is a Delaware corporation having its principal place of business at 5918 Stoneridge Mall Road, Pleasanton, California 94588. Safeway owns and operates retail stores in several states at which it dispenses prescription drugs to the public,

including Nexium. Safeway brings this action in its own behalf and as the assignee of McKesson Corporation ("McKesson"), a pharmaceutical wholesaler, which during the relevant period purchased Nexium directly from Defendant AstraZeneca for resale to Safeway and which has assigned its claims arising out of those purchases to Safeway.

18. Plaintiff Supervalu Inc. ("Supervalu") is a Delaware corporation having its principal place of business at 11840 Valley View Road, Eden Prairie, Minnesota 55344. Supervalu owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Nexium. Supervalu brings this action in its own behalf and as the assignee of McKesson, which during the relevant period purchased Nexium directly from Defendant AstraZeneca for resale to Supervalu and which has assigned its claim arising out of a portion of those purchases to Supervalu.

19. Plaintiff HEB Grocery Company L.P. ("HEB") is a Texas limited partnership having its principal place of business at 646 South Main Avenue, San Antonio, Texas 78204. HEB owns and operates retail stores in several states at which it dispenses prescription drugs to the public, including Nexium. HEB brings this action in its own behalf and as the assignee of Cardinal, which during the relevant period purchased Nexium directly from Defendant AstraZeneca for resale to HEB and which has assigned its claims arising out of those purchases to HEB.

20. Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business in Sodertalje, Sweden.

21. Defendant Aktiebolaget Hassle is a company organized and existing under the laws of Sweden, having its principal place of business in Mölndal, Sweden.

22. Defendant AstraZeneca LP is a limited partnership organized under the laws of Delaware, having its principal place of business in Wilmington, Delaware. AstraZeneca LP

holds an approved New Drug Application from the FDA for a delayed-release esomeprazole magnesium formulation that it sells throughout the United States under the brand name Nexium.

23. Defendants AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP (collectively, "AstraZeneca") are referred to collectively herein as "AstraZeneca.

24. Defendant Ranbaxy Pharmaceuticals, Inc., is a company organized and existing under the laws of Florida, with its principal place of business at 9431 Florida Mining Blvd. East, Jacksonville, Florida, and having its place of business at 600 College Road East, Suite 2100, Princeton, New Jersey. This defendant is a wholly-owned subsidiary of Ranbaxy Laboratories Limited.

25. Defendant Ranbaxy Laboratories Limited is a public limited liability company organized and existing under the laws of India, with a principal place of business located at Plot 90, Sector 32, Gurgaon-122001 (Haryana), India.

26. Defendant Ranbaxy, Inc. is a Delaware corporation, having a place of business at 600 College Road East, Suite 2100, Princeton, New Jersey.

27. Defendants Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, and Ranbaxy, Inc. (collectively, "Ranbaxy") are engaged in the worldwide marketing, production and distribution of generic pharmaceutical products.

28. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation, having its principal place of business at 5 Basel St, P.O. Box. 3190, Petach Tikva 49131, Israel.

29. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454.

30. Defendants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") are the largest generic manufacturers of pharmaceuticals in the world.

31. Defendant Dr. Reddy's Laboratories, Ltd. is an Indian pharmaceutical company with its principal place of business at Door No 8-2-337, Road No 3, Banjara Hills, Hyderabad – 500034, Andhra Pradesh, India.

32. Defendant Dr. Reddy's Laboratories, Inc. is a New Jersey corporation with its principal place of business at 200 Somerset Corp. Blvd., Bridgewater, New Jersey. On information and belief Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. Both entities are referred to collectively herein as "Dr. Reddy's."

33. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

REGULATORY BACKGROUND

The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs

34. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a) and (b).

35. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list in the Orange Book any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents. Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. 21 U.S.C. § 355(b)(1) and (c)(2).

36. The FDA relies completely on the brand name manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

The Hatch-Waxman Amendments

37. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand name drug may instead file an abbreviated new drug application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug.

38. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having

the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

39. Congress enacted the Hatch-Waxman Amendments to expedite the entry of non-infringing generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical companies' incentives to create new and innovative products.

40. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion, with generic drugs accounting for 75% of prescriptions.

Paragraph IV Certifications

41. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

b. that the patent for the brand name drug has expired (a "Paragraph II certification");

c. that the patent for the brand name drug will expire on a particular date and

the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

d. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

42. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of its ANDA simply by suing the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

43. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months.

44. Brand name manufacturers can "game the system" by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files

an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to thirty months. That brand-name manufacturers often sue generics under Hatch-Waxman simply to delay generic competition—as opposed to enforcing a valid patent that is actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products studied.

45. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity "parking." This tactic creates a "bottleneck," because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

Forfeiture Provisions under the MMA

46. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") in order to make it more difficult for brand and generic pharmaceutical companies to conspire to delay the start of the first-filer's 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their products.

47. Under the "failure to market" provision, a first ANDA applicant will forfeit its 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that

qualified the first applicant for exclusivity (*i.e.*, as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

48. Brand name manufacturers and first-filing generics are able to structure their settlements in order to intentionally skirt the failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment settling the litigation that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger a forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action over patents that the brand company did not assert against it in a Paragraph IV Litigation.

Authorized Generics, No-Authorized Generic Agreements, and Exclusive Licenses

49. In an increasing number of instances, brand companies disguise an exclusion payment to a first-filing generic company by agreeing not to launch an "authorized generic" version of the branded drug during the first-filing generic company's initial 180-day marketing exclusivity period. An authorized generic is the branded drug, manufactured just like the branded product, but sold as a generic product under the same approval as the brand product's original NDA. Because the brand manufacturer already has approval to sell its branded drug, it

does not need to file an ANDA, or obtain any additional approvals, to market a chemically identical generic version of the drug.

50. For the brand company, an authorized generic launch during the 180-day period provides a low cost, low risk means to regain some of the monopoly revenue lost from the termination of brand exclusivity that would otherwise go to the generic first-filer. For the generic manufacturer holding a 180-day exclusivity period, however, an authorized generic launch has a substantial impact on revenue. Generic companies generally make about 80% of their total income on a given generic product during the 180-day exclusivity period, and an authorized generic, when launched during the 180-day exclusivity period, captures a substantial portion of total generic sales during that period. Freedom from an authorized generic during the initial 180-day period is thus exceedingly valuable to the generic company holding that exclusivity – it doubles the revenues and profits of that generic company.

51. A generic company holding a180-day exclusivity period may be willing to delay its entry in return for a brand company's agreement to forgo its own revenue stream and forbear from launching an authorized generic during the 180-day exclusivity period. Although a brand company will sacrifice authorized generic product revenue and profits from making a no-authorized generic agreement, it retains far more in branded profits and sales from paying a generic company to delay market entry using a no-authorized generic agreement. In effect, the branded company compensates the generic company by ensuring that it earns higher post-entry sales and profits (which are paid for by Plaintiffs and other purchasers of the generic).

52. No-authorized generic agreements can take a variety of forms. Most commonly, they are structured as an "exclusive license," in which the brand company licenses the first-filing generic to sell a generic drug and agrees not to compete with the generic during the statutory 180-day exclusivity period. These are not genuine exclusive licenses because the brand

company retains the right to sell the branded drug (*i.e.*, it retains the right to sell the drug so long as it does so at the higher, branded, price).

53. In a report by the Federal Trade Commission issued at the request of Congress in 2011 entitled *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, the FTC concluded that no-authorized generic agreements can provide significant value to a first-filer generic company and have become a common form of payment from brands to generics to induce delayed generic entry. The FTC analyzed documents and empirical data covering more than 100 companies and found that the presence of authorized generic competition can reduce the first-filer generic's revenues by more than 50 percent during the 180-day exclusivity period. The FTC found that a generic company makes significantly less when competing with an authorized generic because the authorized generic takes a significant share of generic sales away from the first-filer, and wholesale and retail prices decrease when the first-filer faces an authorized generic.

54. For the first-filer generic, like Ranbaxy, of a $3 billion (or more) branded product like Nexium, the difference between selling the only generic product and competing against an authorized generic during the exclusivity period can amount to hundreds of millions if not billions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic report cites numerous documents from industry participants confirming the financial impact of an authorized generic. No-authorized generic agreements like the one between AstraZeneca and Ranbaxy thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

Generic Versions of Brand-Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly from the Corresponding Brand-Name Versions

55. Typically AB-rated generics are priced significantly below their branded counterparts. Because of the price differentials, and other institutional features of the pharmaceutical industry, generic versions are liberally and substantially substituted by pharmacists presented with a prescription for the brand-name counterpart. In particular, generic drugs that are therapeutically equivalent to their brand name counterparts are given an "AB" rating by the FDA. In every state, pharmacists are permitted (and, in some states, required) to substitute a generically-equivalent product for the brand-name product prescribed, unless the doctor has indicated that the prescription for the brand-name product must be "dispensed as written." Similarly, insurance plans often require or incentivize such substitution. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and pharmacy substitution, and thus the loss of sales volume by the brand-name drug to the corresponding generic, accelerates.

56. Generic competition enables all direct purchasers to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand-name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug to substitute for and otherwise compete with the brand-name drug, and therefore the brand-name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales.

57. Consequently, brand-name drug manufacturers have a strong incentive to use various tactics, including exclusion payment agreements such as the Agreements alleged above and below, to delay the introduction of generic competition into the market.

OPERATIVE FACTS

Defendants' Unlawful Conduct

AstraZeneca Files Paragraph IV Litigation Against Ranbaxy, Teva, and Dr. Reddy's in a Scheme to Monopolize the Relevant Market

58. Nexium is a prescription proton pump inhibitor (PPI) used to treat heartburn and related conditions. The active ingredient in Nexium is esomeprazole magnesium. Its pharmacological profile, and thus its side effect and efficacy profile, is different than other PPIs, H2 blockers and non-prescription antacids that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Nexium, cannot be automatically substituted for Nexium by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Nexium, and thus are not economic substitutes for, nor reasonably interchangeable with, Nexium.

59. On December 3, 1999, AstraZeneca submitted NDA 21-153 seeking FDA approval to market esomeprazole magnesium delayed-release capsules in 20 mg and 40 mg strengths under the brand name Nexium for the healing of erosive esophagitis, maintenance of healing of erosive esophagitis, and treatment of symptomatic gastroesophageal reflux disease. The FDA approved AstraZeneca's NDA for Nexium on February 20, 2001.

60. In connection with its Nexium NDA, AstraZeneca listed fourteen patents in the FDA Orange Book as covering Nexium or a method of using Nexium (the "Nexium patents").

Patent	Expiry
U.S. Patent No. 4,786,505 ("the '505 Patent")	April 20, 2007
U.S. Patent No. 4,853,230 ("the '230 patent")	April 20, 2007

U.S. Patent No. 4,738,974 ("the '974 Patent")	September 1, 2007
U.S. Patent No. 5,877,192 ("the '192 patent")	May 27, 2014
U.S. Patent No. 6,875,872 ("the '872 patent")	May 27, 2014
U.S Patent No. 5,690,960 ("the '960 patent")	November 25, 2014
U.S. Patent No. 5,714,504 ("the '504 patent")	February 3, 2015
U.S. Patent No. 5,900,424 ("the '424 patent")	May 4, 2016
U.S. Patent No. 6,369,085 ("the '085 patent")	May 25, 2018
U.S. Patent No. 7,411, 070 ("the '070 patent")	May 25, 2018
U.S. Patent No. 6,147,103 ("the '103 patent")	October 9, 2018
U.S. Patent No. 6,191,148 ("the '148 patent")	October 9, 2018
U.S. Patent No. 6,166,213 ("the '213 patent")	October 9, 2018
U.S. Patent No. 6,428,810 ("the '810 patent")	November 3, 2019

61. Although the Nexium patents purport to cover, among other things, compounds and pharmaceutical compositions comprised of magnesium salts of esomeprazole, and methods of using those compounds and compositions, there existed a substantial risk that the patents would be invalidated or adjudicated non-infringed upon a challenge from generic manufacturers.

62. Among other reasons for this substantial risk, the Nexium patents are inherently weak because the esomeprazole "invention" described in the various Nexium patents is *prima*

facie obvious in light of the prior art, including, but not limited to, AstraZeneca's predecessor PPI drug, Prilosec.

63. The active ingredient in Prilosec is omeprazole. Omeprazole is a "racemate," which is a substance consisting of equal parts of two different isomers of the same molecule. The different isomers, known as "enantiomers," are non-superimposable mirror images of one another but are otherwise identical. Human hands are commonly used to illustrate this principle. A person's left hand and right hand are non-superimposable mirror images of each other. Pairs of enantiomers share many chemical and physical properties, though they may exhibit very different biologic activity. For example, it is commonly known that one enantiomer of the pair will be more biologically active than the other.

64. A 20 mg dose of the racemate omeprazole contains 10 mg of the left-handed or "S" (for *sinister*, the Latin word for "left-handed") enantiomer and 10 mg of the right-handed or "R" enantiomer. Nexium, which contains esomeprazole, the S-enantiomer of omeprazole, is simply Prilosec without the less active R-enantiomer.

65. Under well-settled patent law principles, a prima facie case of obviousness exists when there is a structural similarity between the claimed compound and prior art compounds, and the prior art gives reason or motivation to make the claimed compound. In the case of Nexium, esomeprazole is clearly prima facie obvious in view of the admittedly prior art racemic omeprazole. And, the evidence establishes that the claims of the Nexium enantiomer patents are invalid as obvious.

66. AstraZeneca faced substantial risk that its Nexium patents would be invalidated through patent litigation. In fact, the European Patent Office has ruled, first in 2006 and then again in 2011, in connection with opposition proceedings brought by generic manufacturers, including at least Generic Defendant Teva, that two European Nexium patents—which are

similar to U.S. Nexium patents—invalid for failing to satisfy the "inventive step" requirement, which is analogous to obviousness under U.S. patent law.

67. A Canadian Court likewise ruled in 2010 that a patent, claiming esomeprazole "having an optical purity of 99.8% or greater," was invalid for lack of sound prediction and obviousness. The Court observed as a basis for its ruling that as of the claim date of May 1993, it was known that omeprazole could be separated into its S- and R- enantiomers, that they would be desirable to use in the treatment of gastric illnesses, that they could be processed in salt form with a magnesium salt, and that a purity of 95.6% (ee) for esomeprazole had been reported as having been achieved in the prior art.

68. By listing the '974 patent, the '505 patent and the '230 patents in the Orange Book, all of which were first generation Prilosec patents, AstraZeneca took the formal position that these three patents covered Nexium. As a matter of these Orange Book submissions, AstraZeneca implicitly admitted that the original omeprazole patents taught the enantiomer, one skilled in the art would have the knowledge from the Prilosec patents to make the enantiomer, and it would be desirable to make the enantiomer.

69. Because the Nexium patents are particularly susceptible to attack on validity grounds, generic companies were eager to apply for FDA approval to market generic versions of Nexium prior to the expiration of the Nexium patents.

AstraZeneca Patent Litigation against Ranbaxy

70. On or about October 14, 2005, Generic Defendant Ranbaxy notified AstraZeneca that it had filed ANDA No. 77-830, seeking to market generic versions of Nexium containing 20 mg and 40 mg of esomeprazole magnesium in delayed-release capsules. Ranbaxy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its

generic Nexium product would not infringe any valid claim of any patent that expired after October 2007 listed in the FDA Orange Book as covering Nexium or a method of using Nexium.

71. On November 21, 2005, AstraZeneca filed suit against Ranbaxy in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, (the "Ranbaxy Litigation"), alleging that Ranbaxy's generic Nexium product would infringe six patents, five of which were Orange Book-listed: the '504 patent; the '192 patent; the '872 patent; the'810 patent; the '085 patent; and U.S. Patent No. 5,948,789 ("the '789 patent").

72. The '789 patent, as a process patent, could not be listed in the Orange Book. Because AstraZeneca did not list the '789 patent in the Orange Book, it was never included in any generic manufacturers' Paragraph IV certification, including Ranbaxy's, and AstraZeneca could not obtain the Hatch-Waxman 30-month stay by bringing an infringement claim on this patent alone.

73. Each of the patents was weak and likely to be adjudicated invalid, unenforceable or non-infringed during the Ranbaxy Litigation.

The Asserted Nexium Patents were Likely to be Ruled Invalid, Unenforceable or Not Infringed

74. Recall that omeprazole is a racemic mixture of two optically active molecules, the S-enantiomer and R-enantiomer. The '504 patent claims a pharmaceutical formulation comprised of solid state alkaline salts of the S-enantiomer, which is also referred to as (-)-omeprazole or esomeprazole. Importantly, not only is racemic omeprazole prior art to the '504 patent, but so are the S-enantiomer and the R-enantiomer. Indeed, the '504 patent itself concedes that these two enantiomers were known and separated no later than 1990 in the *Journal of Chromatography* 532 (1990) at 305-19. Not surprisingly, in reviewing the patent application that would issue as the '504 patent, the examiner at the U.S. Patent and Trademark Office

("PTO") concluded that the salts of the individual enantiomers were invalid as "obvious variants [sic] over the corresponding racemate because of their presence in the racemate."

75. To overcome this objection, AstraZeneca represented to the PTO that "the (-) omeprazole enantiomer, as administered in the form of its alkaline sales, unexpectedly exhibits a different and more advantageous pharmacokinetic profile than the racemic mixture or the (+)-enantiomer of omeprazole," citing a declaration of one of its scientists that it submitted in support of this argument. Unable to challenge the accuracy of these representations, the PTO allowed the '504 patent. Specifically, the PTO relied on AstraZeneca's claim that "the present application and the Anderson declaration prove" that salts of the S-enantiomer demonstrate surprising activity.

76. The FDA, unlike the PTO, had the resources to challenge AstraZeneca's scientific assertions. The FDA later reviewed AstraZeneca's data from its clinical studies and concluded the S-enantiomer not only fails to exhibit surprising activity relative to the racemate, but also fails to achieve any statistically significant improvement over the racemate. Reviewing AstraZeneca's data, the FDA concluded "[s]ince the difference between the esomeprazole 20 mg/qd and the omeprazole 20 mg/qd observed in study 172 was not reproduced in study 174, the observed differences in healing rates and symptom relief for esomeprazole 40 mg and omeprazole 20 mg may reflect differences in *dose* rather than rather than *metabolic or pharmacologic differences*. No clinical comparisons of 40 mg of esomeprazole with 40 mg of omeprazole were performed to quantify the effect of metabolic differences of this dose."

77. The FDA's conclusion is consistent with the findings of other researchers, who had concluded that there was no significant difference in the activity of the single enantiomers of omeprazole as compared to each other and the racemate. *See* Erlandsson, P., *et al*., "Resolution of the Enantiomers of Omeprazole and Some of its Analogues by Liquid Chromotology on a

Triphenylcarbomoylcellulose-based Stationary Phase: The Effect of the Enantiomers of Omeprazole on Gastric Glands. *J. Chromatogr.* 532 (1990) at305-19 ("Erlandsson"); *see also* Cairns *et al.*, *J. of Chromatogr.* 666 (1995) at 323-328, discussing (+)-omeprazole and (-)-omeprazole. In fact, AstraZeneca itself admitted "Erlandsson teaches that the omeprazole racemate is equal in potency to the (-)-enantiomer."

77. Because the S-enantiomer of omeprazole fails to demonstrate sufficiently surprising results, the claims of the '504 patent are obvious in view of the prior art, including various patents directed to the omeprazole racemate.

78. In addition, German patent application DE 4,035,455 renders the '504 patent invalid under §§ 102 and/or 103. This application disclosed a method for producing "optically pure compounds from diastereomers" of a class of compounds which included omeprazole and that they could be used as active ingredients to treat gastric problems.

79. The claims of the '192 and the '872 patent share the same substantial weaknesses as the '504 patent, and for the same reasons. Both patents are so closely related to the '504 patent that the PTO rejected the claims of the former patents as merely obvious variants of the latter. To overcome this rejection, AstraZeneca filed a terminal disclaimer, conceding the similarity of the claims and disclaiming any patent term for the '192 and the '872 patent that would extend beyond the patent term of the '504 patent.

80. The '192 patent and the '872 patent were also likely to be invalid under 35 U.S.C. §§ 102 and/or 103 in view of, *inter alia*, WO 94/27988 (Example 10), which AstraZeneca itself has admitted discloses "[n]ovel salts of the single enantiomers of omeprazole." *See, e.g.*, U.S. Patent No. 5,817, 338, Col. 1, Lines 23-23.

81. The '085 patent and '810 patent were highly specific and narrow formulation patents that, on that basis alone, likely never would have been infringed. Further, they were

likely to be adjudicated invalid or unenforceable in view of AstraZeneca's disclosures of the hydrates in the '960 patent and the '424 patent.

82. In addition, Ranbaxy maintained, even in settlement of AstraZeneca's litigation against it, that the '085 patent and the '810 patent would never be infringed by its product.

83. The '789 patent provided little protection against would-be generic entrants. Numerous prior references – both for omeprazole products and for esomeprazole itself – already taught processes by which to isolate the omeprazole enantiomers. At most, the '789 patent ostensibly teaches only one, particular asymmetric process to create an isolated omeprazole enantiomer, and that particular process still had a yield of less than 50%. (An asymmetric process means going right to making the isolated enantiomer without first making the racemic compound.) And other claims in the '789 patents were for compounds which are simply other structurally-related sulphoxides provide no utility to support the claimed inventions.

84. In short, the '789 patent was likely to either be declared invalid or unenforceable, or non-infringed by Ranbaxy.

85. AstraZeneca never brought litigation against Ranbaxy on the other nine Nexium Patents it had listed in the Orange Book: the '974 patent, the '505 patent, the '230 patent, the '960 patent, the '424 patent, the '103 patent, the '213 patent, the '148 patent and the '070 patent. These nine patents would not a bar Ranbaxy's entry into the market in April 2008.

86. There was a substantial uncertainty that AstraZeneca would prevail in asserting infringement claims against Ranbaxy. The Nexium patents, absent the unlawful agreement, would not a bar to Ranbaxy's entry into the market in April 2008.

AstraZeneca Patent Litigation against Teva

87. On or about January 26, 2006, Generic Defendant Teva notified AstraZeneca that it had filed ANDA No. 78-003, seeking to market generic versions of Nexium containing 20 mg

and 40 mg of esomeprazole magnesium in delayed-release capsules. Teva's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of any patent listed in the FDA Orange Book as covering Nexium or a method of using Nexium.

88. On March 8, 2006, AstraZeneca filed suit against Teva in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Teva's generic Nexium product would infringe five of the patents listed in the Orange Book for Nexium: the '504; '192; '872; '810; and '085 patents (the "Teva Litigation"). Subsequently, AstraZeneca amended its complaint by dropping its allegation that Teva infringed the '810 patent and adding an allegation that Teva infringed the '789 patent and the '070 patent.

89. For reasons previously stated, the '504, '872, '085, '192 and '789 patents were weak and likely to be to be adjudicated invalid, unenforceable or non-infringed during the Teva Litigation

90. The '070 patent – a continuation of the '085 patent – was so closely related to the '085 patent that the PTO initially rejected the '070 patent on the basis of obviousness and statutory (35 U.S.C. § 101) double patenting because certain claims of the '070 patent were shared by – in fact, were identical to – claims in the '085 patent. The '070 patent is also subject to the same weaknesses and basis for invalidity or non-infringement as the '085 patent.

91. AstraZeneca never brought litigation against Teva on the other eight Nexium patents it had listed in the Orange Book: the '974 patent, the '505 patent, the '230 patent, the '960 patent, the '424 patent, the '103 patent, the '213 patent, and the '148 patent. These eight patents were not a bar to Teva's entering the market by late 2008.

92. There was a substantial uncertainty that AstraZeneca would prevail in asserting infringement claims against Teva. The Nexium patents, absent the unlawful agreements, would

not bar Teva's early entry into the market.

AstraZeneca Patent Litigation against Dr. Reddy's

93. On August 17, 2006, Generic Defendant Dr. Reddy's notified AstraZeneca that it had filed ANDA No. 78-279, seeking to market generic versions of Nexium containing 20 mg and 40 mg of esomeprazole magnesium in delayed-release capsules. Dr. Reddy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of seven of the fourteen Orange Book-listed patents, including the '085 and the '810 patents. On December 4, 2007, Dr. Reddy's amended its ANDA to assert that its proposed generic Nexium product would not infringe the '504, '192 or '872 patents, or that those patents were invalid.

94. On January 17, 2008, AstraZeneca filed suit against Dr. Reddy's in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Dr. Reddy's generic Nexium product would infringe three of the patents listed in the Orange Book for Nexium: the '504, '872, and '085 patents (the "Dr. Reddy Litigation"). In reply to Dr. Reddy's answer, AstraZeneca also asserted that Dr. Reddy's proposed generic Nexium product would infringe the '192 patent.

95. Subsequently, AstraZeneca dropped its claim of infringement against Dr. Reddy's for the '085 patent and entered into a Consent Agreement in which the court entered a final decision that Dr. Reddy's "ANDA Products do not infringe any claim of the '085 patent and accordingly judgment is entered in favor of [Dr. Reddy's] on Astra's Third Claim For Relief."

96. On May 19, 2008, Dr. Reddy filed a complaint for a declaratory judgment against AstraZeneca in the United States District Court for the District of New Jersey seeking a declaratory judgment that its "commercial manufacture, use, offer for sale, sale or importation of its generic equivalent of Nexium or the active ingredient thereof would not infringe" the '960

patent, the ’424 patent, the ’103 patent, the ’213 patent, the ’148 patent, or the ’810 patent – patents for which AstraZeneca did not assert infringement against Dr. Reddy’s within the 45 days following Dr. Reddy’s notice of Paragraph IV certification. In its Answer, AstraZeneca admitted that Dr. Reddy’s proposed esomeprazole magnesium delayed release capsule products “do not infringe the ‘148 patent” and “do not infringe the ‘810 patent.”

97. The ‘504, ‘872, and ‘192 patents were weak and likely to be adjudicated invalid, unenforceable or non-infringed.

98. AstraZeneca never brought litigation against Dr. Reddy’s on ten Nexium Patents it had listed in the Orange Book: the ’974 patent, the ‘505 patent, the ‘230 patent, the ’960 patent, the ’424 patent, the ’103 patent, the ’213 patent, the ’148 patent, the ’810 patent, and the ’070 patent. These ten patents were not a bar to Dr. Reddy’s entry into the market.

99. There was a substantial uncertainty that AstraZeneca would prevail in asserting infringement claims against Dr. Reddy’s. The Nexium patents, absent the unlawful agreements, would not bar Dr. Reddy’s’ early entry into the market.

AstraZeneca Avoided Likely Patent Litigation Losses by Buying Off its Competition

100. AstraZeneca’s actions against the Generic Defendants were consolidated, and the Generic Defendants conducted discovery supporting a host of defenses focusing on: (1) the enforceability of the Nexium patents; (2) the validity of the Nexium patents’ claims; and (3) the strength of AstraZeneca’s infringement allegations. AstraZeneca and the Generic Defendants entered into the Exclusion Payment Agreements before any dispositive motions relating to the Generic Defendants’ substantive challenges to the patents were decided.

101. To prevent generic entry using just its patents (rather than pay-offs), AstraZeneca would have had to show that each of the generic Nexium products infringed its patents and to defeat each of the Generic Defendants’ invalidity arguments. AstraZeneca instead decided to

protect its monopoly by paying all of the Generic Defendants to withdraw their challenges to the validity and enforceability of its patents and delay their introduction of generic Nexium. And that is precisely what it has done, in concert with the Generic Defendants.

102. As described below, these settlement agreements constituted not only an agreement to delay generic entry between AstraZeneca and an individual Generic Defendant but also an agreement not compete between and among the Generic Defendants as brokered by AstraZeneca. Each of the agreements contained the same agreed upon delayed entry date as well as a provision enabling a settling Generic Defendant to enter earlier if one of its generic competitors continued to litigate and established that the Nexium patents were invalid or not infringed.

AstraZeneca and Ranbaxy Enter an Exclusion Payment Agreement

103. On or about April 14, 2008, shortly after discovery ended and before the court could issue any substantive rulings, AstraZeneca and Ranbaxy entered into the AstraZeneca/Ranbaxy Exclusion Payment Agreement. Pursuant to that Agreement, AstraZeneca ended its litigation against first-filer Ranbaxy, and a consent judgment was entered on the exact same day that the 30-month stay of FDA approval of Ranbaxy's generic Nexium product expired.

104. Under the Exclusion Payment Agreement, Ranbaxy agreed to (a) admit that the '504, '192, '789, '085, '810, and '872 patents were enforceable and valid; (b) admit that its generic Nexium products would infringe the '504, '192, '789, and '872 patents (but not the '810 or '085 patents); and (c) delay launching its generic Nexium product until May 27, 2014 unless otherwise specifically authorized by the Agreement (which included earlier entry by another generic).

105. As the *quid pro quo* for Ranbaxy's agreement to drop its challenge to the Nexium

patents listed above and to delay entry of its generic Nexium product until May 27, 2014, AstraZeneca agreed, pursuant to the Agreement, to pay Ranbaxy over a billion dollars.

106. Shortly after the settlement, Ranbaxy's Chief Executive Officer, Malvinder Singh, boasted that the Agreement would give Ranbaxy as much as *$1.5 billion* in revenue between the date of the Agreement and the end of its 180-day marketing exclusivity in 2014. Singh characterized the Agreement as "the biggest and most comprehensive settlement to date by any generic company globally." Upon information and belief, AstraZeneca has already paid Ranbaxy millions of dollars under their Agreement.

107. Although AstraZeneca's payments to Ranbaxy under the Agreement are characterized as payments for Ranbaxy's performance of manufacturing and distribution services for AstraZeneca, those characterizations are pretextual. In particular, AstraZeneca licensed Ranbaxy to market generic delayed-release esomeprazole magnesium during Ranbaxy's first-filer 180-day period of generic market exclusivity and agreed not to sell an authorized generic in competition with Ranbaxy—*i.e.*, a no-authorized generic agreement. This agreement constituted a payment of substantial consideration from AstraZeneca to Ranbaxy, nearly one billion dollars. In a press statement issued at the time the Exclusion Payment Agreement was publicly disclosed, Ranbaxy stated that the bulk of the revenues from the Exclusion Payment Agreement would accrue in 2014, when Ranbaxy would be able to launch a generic version of Nexium in the United States with a 180-day exclusivity period.

108. This and other payments from AstraZeneca to Ranbaxy were for Ranbaxy's agreement to delay generic competition to Nexium for over 6 years. Absent Ranbaxy's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have made the no-authorized generic agreement or agreed to designate Ranbaxy as a supplier of Nexium and Nexium API or as the authorized generic distributor for Plendil or Prilosec and/or

would not have agreed to the price and/or terms that it did under those provisions of the Agreement. AstraZeneca paid Ranbaxy for delayed market entry of generic Nexium.

AstraZeneca Delays Legitimate Effects to "Uncork" the Bottleneck

109. On April 30, 2008, shortly after AstraZeneca and Ranbaxy entered their Agreement, Generic Defendant Teva filed a declaratory judgment action against AstraZeneca seeking a ruling of invalidity and non-infringement regarding the remaining Orange Book-listed patents that AstraZeneca did not sue Teva for infringing in connection with Teva's generic Nexium ANDA. Teva filed its declaratory judgment action to obtain a favorable judgment regarding all Orange Book-listed Nexium patents and thus uncork the FDA approval bottleneck caused by AstraZeneca's settlement with first-filer Ranbaxy, which (absent some other forfeiture event) ensures that Ranbaxy's 180-day marketing exclusivity will not be triggered until May 27, 2014. Dr. Reddy's followed in May 2008 with its own declaratory judgment action seeking a ruling of non-infringement with respect to the unasserted Orange Book-listed patents.

110. In response to AstraZeneca's motion to dismiss its declaratory judgment action for lack of jurisdiction, Teva accused AstraZeneca of gaming the system "to take advantage of what [Teva] contends is an *invalid and illegitimate patent monopoly*." According to Teva, as a result of the exclusion payment agreement between AstraZeneca and Ranbaxy, if it could not "challenge the patents in suit, the patents will represent a six-year barrier to anyone entering the market, regardless of whether they are valid or would be infringed. In those circumstances, [Teva] would be precluded from marketing its product and the public would not have access to lower-priced esomeprazole *even though no legitimate patent rights protect defendants' monopoly*."

111. The court denied in substantial part AstraZeneca's motion to dismiss the declaratory actions, but granted AstraZeneca's motion to stay the declaratory actions pending

resolution of the main infringement action. Although on reconsideration the court permitted the declaratory actions to proceed, AstraZeneca succeeded in delaying by approximately six months Teva's and Dr. Reddy's efforts to obtain a court judgment that could allow them to enter the market ahead of May 27, 2014.

AstraZeneca and Teva Enter an Exclusion Payment Agreement

112. Eventually AstraZeneca was able to buy off Teva's patent challenges as well.

113. Although claim construction was briefed during the summer of 2009, AstraZeneca and Teva, pursuant to that Agreement, repeatedly asked the court to postpone construing the contested claims of the Nexium patents. The protracted delay meant that the court had issued no substantive rulings as of January 7, 2010. On or about that date, AstraZeneca and Teva entered into the AstraZeneca/Teva Exclusion Payment Agreement, which ended the litigation between AstraZeneca and Teva.

114. Under the Exclusion Payment Agreement, Teva agreed to: (a) admit that all patents then listed in the Orange Book as covering Nexium "are all enforceable and valid with respect to certain products;" (b) admit that its generic Nexium product would infringe the '504, '192, '789, '085, '872 and '070 patents; and (c) delay launching its generic Nexium until May 27, 2014 unless otherwise specifically authorized by the Agreement (which included earlier entry by another generic).

115. As the *quid pro quo* for Teva's agreement to drop its challenge to the Nexium patents and to delay entry of its generic Nexium products until May 27, 2014, pursuant to the AstraZeneca/Teva Exclusion Payment Agreement, AstraZeneca agreed to pay Teva. That payment came in the form of AstraZeneca's forgiveness of Teva from a patent infringement liability.

116. Teva had an enormous contingent liability to AstraZeneca. On September 9,

2004, Teva had commenced an "at risk" launch of generic Prilosec, which was manufactured by its marketing partner, Impax. In 2008, the Federal Circuit affirmed the district court's ruling that the Prilosec patents were valid and infringed by Impax's generic Prilosec product. Because Teva and Impax shared the risk with respect to any damages associated with the sale of the generic Prilosec product Teva would owe AstraZeneca massive infringement damages resulting from years of infringing generic Prilosec sales – in the hundreds of millions of dollars or more. As part of their Exclusion Payment Agreement, Teva and AstraZeneca agreed that Teva would pay only a non-financially material amount to account for Teva's past infringing Prilosec sales. By forgiving virtually all of Teva's contingent liability to AstraZeneca with respect to a different drug, AstraZeneca paid Teva.

117. The true purpose and effect of the payment to Teva was to delay generic competition to Nexium until May 27, 2014. Absent Teva's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have forgiven Teva substantially all of the contingent liability and/or would not have done so on the terms that it did. AstraZeneca paid Teva for delayed market entry of generic Nexium.

AstraZeneca and Dr. Reddy's Enter an Exclusion Payment Agreement

118. On or about January 28, 2011, before the court could issue any dispositive decision regarding the validity or infringement of the Nexium patents, AstraZeneca and Dr. Reddy's entered the AstraZeneca/Dr. Reddy's Exclusion Payment Agreement, which ended the litigation between AstraZeneca and Dr. Reddy's and delayed entry of Dr. Reddy's generic Nexium products until May 27, 2014 unless specifically authorized by the Agreement (which included earlier entry by another generic). Dr. Reddy's made no admissions regarding validity or infringement.

119. As the *quid pro quo* for Dr. Reddy's agreement to drop its challenge to the

Nexium patents and to stay out of the Nexium market until May 27, 2014, AstraZeneca agreed to pay Dr. Reddy's by forgiving Dr. Reddy's from an outstanding contingent liability.

120. Dr. Reddy's had a substantial contingent liability to AstraZeneca. Dr. Reddy's had launched its generic version of AstraZeneca's Accolate product "at risk" in November of 2010, following a summary judgment opinion in Dr. Reddy's favor that AstraZeneca had appealed at the time of the Agreement. By agreeing, as part of and simultaneously with the Exclusion Payment Agreement, to drop its appeal and thereby remove the risk that Dr. Reddy's would have to pay substantial damages with respect to its generic Accolate sales, AstraZeneca paid Dr. Reddy's under the Agreement.

121. The true purpose and effect of the payment to Dr. Reddy's was to delay generic competition to Nexium until May 27, 2014. Absent Dr. Reddy's agreement to delay entry into the market with generic Nexium, AstraZeneca would not have forgiven Dr. Reddy's of the contingent liability against it and/or would not have done so on the terms that it did. AstraZeneca paid Dr. Reddy's for delayed market entry of generic Nexium.

122. By paying Teva and Dr. Reddy's not to market their generic Nexium products before May 27, 2014, and by doing so before the court could rule on the validity or infringement of the Nexium patents, AstraZeneca ensured that the second and third ANDA-filers could not dislodge the FDA approval bottleneck created by its Agreement with first-filer Ranbaxy.

Anticompetitive Purpose and Effect of the Agreements

123. The agreements have enabled AstraZeneca and the Generic Defendants to: (a) preclude the entry of less expensive generic versions of Nexium products in the United States; (b) fix, raise, maintain or stabilize the price of Nexium products; (c) permit AstraZeneca to maintain a monopoly in the U.S. market for Nexium products; (d) allocate 100% of the U.S. market for delayed-release esomeprazole magnesium to AstraZeneca; and (e) allocate 100% of

United States generic Nexium sales to Ranbaxy during the first 180 days of generic sales.

124. But for the agreements: (i) Ranbaxy (and/or another ANDA filer) would have received final marketing approval from the FDA on or about April 14, 2008, Ranbaxy and/or another ANDA filer would have begun selling AB-rated versions of Nexium shortly thereafter, and AstraZeneca would have simultaneously launched an authorized generic version of Nexium; and (ii) an increasingly competitive market for delayed-release esomeprazole magnesium would have thereafter emerged as additional generic manufacturers entered the market.

125. Defendants' unlawful concerted action has delayed or prevented the sale of generic Nexium in the United States, and unlawfully enabled AstraZeneca to sell Nexium at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Nexium would already have occurred. One or more of the Generic Defendants would have already entered with its generic version of Nexium, and AstraZeneca would have simultaneously entered with an authorized generic version of Nexium.

TRADE AND COMMERCE

126. Defendants' efforts to monopolize and restrain competition in the market for delayed-release esomeprazole have occurred in and have substantially affected interstate commerce.

127. At all material times, AstraZeneca manufactured, promoted, distributed, and sold substantial amounts of branded Nexium in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

MONOPOLY POWER AND MARKET DEFINITION

128. At all relevant times, AstraZeneca had monopoly power over delayed-release esomeprazole magnesium because it had the power to maintain the price of the drug it sold as Nexium at supracompetitive levels without losing substantial sales to other products prescribed

and/or used for the same purposes as Nexium, with the exception of AB-rated generic versions of Nexium.

129. A small but significant, non-transitory price increase for Nexium by AstraZeneca would not have caused a significant loss of sales.

130. Nexium does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Nexium.

131. Because of, among other reasons, its use and varying ability to heal erosive esophagitis, maintain the healing of erosive esophagitis, and treat symptomatic gastroesophageal reflux disease, Nexium is differentiated from all products other than AB-rated generic versions of Nexium.

132. AstraZeneca needed to control only Nexium and its AB-rated generic equivalents, and no other products, in order to maintain the price of Nexium profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Nexium would render AstraZeneca unable to profitably maintain its current prices of Nexium without losing substantial sales.

133. AstraZeneca also sold Nexium at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

134. Defendants have had, and exercised, the power to exclude and restrict competition to Nexium and AB-rated bioequivalents.

135. AstraZeneca, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

136. To the extent that Plaintiffs are legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, Plaintiffs allege that the

relevant market is delayed-release esomeprazole magnesium (*i.e.*, Nexium and its AB-rated generic equivalents). During the period relevant to this case, AstraZeneca has been able to profitably maintain the price of delayed-release esomeprazole magnesium well above competitive levels.

137. The relevant geographic market is the United States and its territories.

138. At all relevant times, AstraZeneca's market share in the relevant market was and remains 100%.

MARKET EFFECTS

139. Ranbaxy's ANDA was in approvable condition as of February 5, 2008, when it received tentative approval. The FDA issues tentative approval only when it determines that an ANDA would otherwise be ready for final approval but for a 30-month stay. Were it not for the AstraZeneca/Ranbaxy Agreement, Ranbaxy would have received final FDA approval on or about April 14, 2008, the date the 30-month stay of FDA approval expired. Generic Nexium products would have entered the market shortly thereafter.

140. The FDA has not given Ranbaxy's Nexium ANDA final approval solely because the FDA knows that the AstraZeneca/Ranbaxy Exclusion Payment Agreement prevents Ranbaxy from selling generic Nexium until May 27, 2014. By practice, the FDA organizes its priorities around "rate limiters," and the AstraZeneca/Ranbaxy Agreement is a rate limiter that has caused the FDA to wait to issue formal, written approval to Ranbaxy's ANDA. Defendants' Exclusion Payment Agreements had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Nexium from generic competition. Defendants' actions allowed AstraZeneca to maintain a monopoly and to exclude competition in the market for delayed-release esomeprazole magnesium, to the detriment of Plaintiffs and other purchasers of the drug.

141. Defendants' Exclusion Payment Agreements have delayed generic competition and unlawfully enabled AstraZeneca to sell Nexium without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Nexium by April 14, 2008 or shortly thereafter, and AstraZeneca would have simultaneously launched an authorized generic version of Nexium.

142. The generic manufacturers seeking to sell generic Nexium had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

143. Defendants' Exclusion Payment Agreements, which delayed introduction into the United States marketplace of generic versions of Nexium, have caused Plaintiffs to pay more than they would have paid for delayed-release esomeprazole magnesium absent Defendants' illegal conduct.

144. But for the Exclusion Payment Agreements, Plaintiffs would have paid less for delayed-release esomeprazole magnesium by (a) substituting purchases of less-expensive generic Nexium for their purchases of more-expensive branded Nexium and/or (b) receiving discounts on their remaining branded Nexium purchases.

145. Moreover, due to Defendants' Exclusion Payment Agreements, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of Nexium, and/or (b) challenging the validity or infringement of the Nexium patents in court.

146. Thus, Defendants' unlawful conduct and overarching scheme deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to ensure.

147. During the relevant period, Plaintiffs or their assignors purchased substantial amounts of Nexium directly from AstraZeneca. As a result of Defendants' illegal Exclusion Payment Agreements as alleged herein, Plaintiffs were compelled to pay, and did pay, artificially inflated prices for their delayed-release esomeprazole magnesium requirements. This injury is of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' acts unlawful.

148. As a consequence of Defendants' unlawful conduct and overarching scheme, Plaintiffs have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

149. Defendants' unlawful conduct threatens continuing loss and damage to Plaintiffs unless enjoined by this Court.

150. The limitations period applicable to Plaintiffs' claims has been tolled since the filing of the first direct purchaser class action on behalf of a class of purchasers that includes Plaintiffs or their assignors. *See Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 176 n.13 (1974) ("commencement of a class action tolls the applicable statute of limitations as to all members of the class").

CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 2
(MONOPOLIZATION AND MONOPOLISTIC SCHEME)

151. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 150 above. This claim is asserted against AstraZeneca only.

152. At all relevant times, AstraZeneca possessed monopoly power in the relevant market.

153. Through an overarching anticompetitive scheme, as alleged extensively above, AstraZeneca willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, including but not limited to, executing, implementing and otherwise complying with the Agreements with Ranbaxy, Teva and Dr. Reddy's, in violation of section 2 of the Sherman Act.

154. It was AstraZeneca's conscious object to control prices and exclude competition in the relevant market by and through the overarching anticompetitive scheme.

155. As a direct and proximate result of AstraZeneca's illegal and monopolistic conduct, as alleged herein, Plaintiffs have suffered antitrust injury as alleged above.

CLAIM II: VIOLATION OF 15 U.S.C. § 2
(ATTEMPT TO MONOPOLIZE)

156. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 150 above. This claim is asserted against AstraZeneca only.

157. AstraZeneca possesses monopoly power in the relevant market, or possesses a dangerous probability of success in achieving monopoly power in the relevant market.

158. With the specific intent to achieve a monopoly, AstraZeneca willfully maintained its monopoly in the relevant market by its overarching scheme as described herein, including, but not limited to, executing, implementing, and otherwise complying with the Agreements with Ranbaxy, Teva, and Dr. Reddy's, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

159. As a result of AstraZeneca's unlawful exclusionary conduct, generic competition has been suppressed and Plaintiffs have been overcharged for delayed-release esomeprazole magnesium, as alleged above.

160. As a direct and proximate result of AstraZeneca's anticompetitive conduct, as alleged herein, Plaintiffs have suffered antitrust injury as alleged above.

CLAIM III: VIOLATION OF 15 U.S.C. § 1
(CONSPIRACY IN RESTRAINT OF TRADE—ASTRAZENECA/RANBAXY)

161. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 150 above. This claim is asserted against Defendants AstraZeneca and Ranbaxy.

162. In or about April 2008 and at times prior to the formal execution thereof, AstraZeneca and Ranbaxy entered into the AstraZeneca/Ranbaxy Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to pay Ranbaxy substantial consideration in exchange for Ranbaxy's agreement to delay bringing its generic version of Nexium to the market, the purpose and effect of which were to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States to AstraZeneca; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for 6 years or more; (c) fix the price at which direct purchasers would pay for delayed-release esomeprazole magnesium at supracompetitive levels; and (d) allocate 100% of United States generic Nexium sales to Ranbaxy during the first 180 days of generic sales.

163. The Agreement harmed Plaintiffs as set forth above.

164. The Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

165. AstraZeneca and Ranbaxy are *per se* liable for the Agreement and/or are liable under a "quick look" and/or rule of reason standard.

166. There is and was no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payment that outweighs its harmful effect. Even if there were some conceivable such justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

167. As a direct and proximate result of AstraZeneca's and Ranbaxy's anticompetitive conduct, as alleged herein, Plaintiffs have suffered antitrust injury as alleged above.

CLAIM IV: VIOLATION OF 15 U.S.C. § 1
(CONSPIRACY IN RESTRAINT OF TRADE—ASTRAZENECA/TEVA)

168. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 150 above. This claim is asserted against Defendants AstraZeneca and Teva.

169. In or about January 2010, and at times prior to the formal execution thereof AstraZeneca and Teva entered into the AstraZeneca/Teva Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to pay Teva substantial consideration in exchange for Teva's agreement to delay bringing its generic version of Nexium to the market, the purpose and effect of which were to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States to AstraZeneca; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for 4 years or more; and (c) fix the price at which direct purchasers would pay for delayed-release esomeprazole magnesium at supracompetitive levels.

170. The Agreement harmed Plaintiffs as set forth above.

171. The Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

172. AstraZeneca and Teva are *per se* liable for the Agreement and/or are liable under a "quick look" and/or rule of reason standard.

173. There is and was no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payment that outweighs its harmful effect. Even if there were

some conceivable such justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

174. As a direct and proximate result of AstraZeneca's and Teva's anticompetitive conduct, as alleged herein, Plaintiffs have suffered antitrust injury as alleged above.

CLAIM V: VIOLATION OF 15 U.S.C. § 1
(CONSPIRACY IN RESTRAINT OF TRADE—ASTRAZENECA/DR. REDDY'S)

175. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 150 above. This claim is asserted against Defendants AstraZeneca and Dr. Reddy's.

176. Beginning in January 2011, and at times prior to the formal execution thereof, AstraZeneca and Dr. Reddy's entered into the AstraZeneca/Dr. Reddy's Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which AstraZeneca agreed to pay Dr. Reddy's substantial consideration in exchange for Dr. Reddy's agreement to delay bringing its generic version of Nexium to the market, the purpose and effect of which were to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States to AstraZeneca; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for 3 years or more; and (c) fix the price at which direct purchasers would pay for delayed-release esomeprazole magnesium at supracompetitive levels.

177. The Agreement harmed Plaintiffs as set forth above.

178. The Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

179. AstraZeneca and Dr. Reddy's are *per se* liable for the Agreement and/or are liable under a "quick look" and/or rule of reason standard.

180. There is and was no legitimate, nonpretextual, procompetitive business justification for the Exclusion Payment that outweighs its harmful effect. Even if there were some conceivable such justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

181. As a direct and proximate result of AstraZeneca's and Dr. Reddy's anticompetitive conduct, as alleged herein, Plaintiffs have suffered antitrust injury as alleged above.

CLAIM VI: VIOLATION OF 15 U.S.C. § 1
(CONSPIRACY IN RESTRAINT OF TRADE—ALL DEFENDANTS)

182. Plaintiffs hereby incorporate by reference the allegations in paragraphs 1 through 150 above. This claim is asserted against all Defendants.

183. By entering into the Exclusion Payment Agreements, AstraZeneca orchestrated and brokered an agreement between and among the Generic Defendants not to compete with each other or with AstraZeneca, which constituted a continuing illegal contract, combination and conspiracy in restraint of trade. AstraZeneca agreed to pay each of the Generic Defendants substantial consideration in exchange for their agreement with AstraZeneca, and between and among each other, to delay bringing their generic versions of Nexium to the market until May 27, 2014, the purpose and effect of which was to: (a) allocate 100% of the market for delayed-release esomeprazole magnesium in the United States to AstraZeneca; (b) prevent the sale of generic versions of Nexium in the United States, thereby protecting Nexium from any generic competition for 6 years or more; and (c) fix the price at which direct purchasers would pay for delayed-release esomeprazole magnesium at supracompetitive levels.

184. This agreement harmed Plaintiffs as set forth above.

185. This agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

186. There is and was no legitimate, nonpretextual, procompetitive business justification for this agreement that outweighs its harmful effect. Even if there were some conceivable such justification, this agreement was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

187. As a direct and proximate result Defendants' agreement, as alleged herein, Plaintiffs have suffered antitrust injury as alleged above.

CLAIM VII: VIOLATION OF 15 U.S.C. § 2
(CONSPIRACY TO MONOPOLIZE—ALL DEFENDANTS)

188. Plaintiffs hereby incorporate by reference the allegations contained in paragraphs 1 through 150 above. This claim is asserted against all Defendants.

189. At all relevant times, AstraZeneca possessed monopoly power in the relevant market.

190. Through an overarching anticompetitive scheme, including the Exclusion Payment Agreements between AstraZeneca, on the one hand, and Ranbaxy, Teva, and Dr. Reddy's, on the other, Defendants conspired to maintain AstraZeneca's monopoly power in the relevant market in order to block and delay market entry of delayed-release esomeprazole magnesium, *i.e.*, AB-rated generic versions of Nexium. The unlawful Exclusion Payment Agreements between AstraZeneca and the Generic Defendants allocated all sales of delayed-release esomeprazole magnesium in the United States to AstraZeneca; delayed the sales of generic Nexium products; and fixed the price which Plaintiffs would pay for delayed-release esomeprazole magnesium at the high, branded price.

191. The goal, purpose and/or effect of the conspiracy was to maintain and extend AstraZeneca's monopoly power in the United States market for delayed-release esomeprazole magnesium in violation of Sherman Act Section 2, 15 U.S.C. § 2. The conspiracy prevented and/or delayed generic competition to Nexium and enabled AstraZeneca to continue charging supracompetitive prices for Nexium without a substantial loss of sales.

192. Defendants knowingly and intentionally conspired to maintain and enhance AstraZeneca's monopoly power in the relevant market.

193. Defendants specifically intended that their conspiracy would maintain AstraZeneca's monopoly power in the relevant market.

194. As a direct and proximate result of Defendants' concerted conduct, as alleged herein, Plaintiffs have suffered antitrust injury as alleged above.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A judgment for three times their actual damages, as determined by a jury at trial;

B. Permanent injunctive relief enjoining Defendants from continuing their unlawful conduct and requiring them to take affirmative steps to dissipate the effects of their prior conduct;

C. The costs of this suit, including reasonable attorneys' fees as provided by law; and

D. Such other and further relief as the Court deems just and appropriate.

JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

Respectfully submitted,

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